USSN 0 752,844 Docket No. 3041 2000221

CERTIFICATE OF HAND DELIVERY

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of: CHATTERIEE et al.

Serial No.: 08/752,844

Filing Date: November 21, 1996

For: MONOCLONAL ANTIBODY 1A7 AND USE

FOR THE TRBATMENT OF MELANOMA AND

SMALL CELL CARCINOMA

Art Unit:

1806

Examiner:

Julie Reeves, Ph.D.

RECEIVED

nct 7 1997

MATRIX CUSTOMER SERVICE CENTER

DECLARATION BY SUNIL K. CHATTERJEE

REGARDING SEQUENCE DATA

Assistant Commissioner for Patents Washington, D.C. 20231

Dear Sir:

I, SUNIL K. CHATTERJEE. Ph.D., do hereby declare as follows:

1. I am a named inventor on this patent application. I am a member of the Markey Cancer Center in Lexington, and am an Associate Professor in the Department of Internal Medicine, University of Kentucky. My research expertise includes the field of molecular biology and genetic engineering.

2. I determined the sequence of the variable regions of monoclonal antibody 1A7, as detailed in the first part of Example 2 of the application.

Messenger RNA was isolated from the antibody-producing cell line designated 1A7, which is light and heavy chain variable region encoding regions were separately amplified by PCR using specific primers, subcloned into pT7 plasmid, and used to transform competent cells. The DNA sequence of the double stranded plasmid was determined using a sequencing kit according to manufacturer's directions.

The amino acid sequence for the light and heavy chain variable regions was predicted from the polynucleotide sequence by applying the genetic code to the corresponding open reading frame. Confirmation was obtained by sequencing the first 10-15 amino acids of the light and heavy chains of the isolated antibody by automated Edman degradation.

3. While translating the polynucleotide sequence of the heavy chain into the protein sequence, an inadvertent error was introduced at one amino acid position.

The polynucleotide sequence was entered into a computer, which provided an automated translation into the amino acid sequence, using three-letter abbreviations for the amino acids. I then converted the three-letter abbreviations into single-letter abbreviations.

The last codon for the heavy chain CDR3 region is "TAC". The computer program correctly translated this codon into "Tyr", the abbreviation for Tyrosine. In converting this into the single-letter abbreviation, I mistakenly recorded a "W" (the abbreviation for Tryptophan) rather than a "Y" (the abbreviation for Tyrosine). Both amino acids start with the letter "T".

This inadvertent error is reflected in Figure 2 as originally filed in this patent application.

4. I was informed that the codon did not correspond to the amino acid translation at this position by the patent attorneys at Morrison & Foerster after the filing of parent





application USSN 08/591,196. I understand they discovered this error while preparing a sequence listing on diskette for the parent application for filing with the Patent Office.

- 5. I have reviewed my notes and confirmed that the correct codon at this position is TAC, and the correct amino acid translation is "Y".
- 6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing therefrom.

10/3/97

Date

Sunil K. Chatterjee, Ph.D.

